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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/783,628	02/20/2004	Ricardo E. Paxson	MWS-108	7206

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EXAMINER

ZHOU, SHUBO

ART UNIT	PAPER NUMBER
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1631

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/783,628

Applicant(s)

PAXSON ET AL.

Examiner

Shubo (Joe) Zhou

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-87 is/are pending in the application.
- 4a) Of the above claim(s) 1-7, 13-14, 19, 21, 23-25, 31-32, 38-39, 44, 46, 48-51, and 68-76 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-12, 15-18, 20, 22, 26-30, 33-37, 40-43, 45, 47, 52-67 and 77-87 is/are rejected.
- 7) ☒ Claim(s) 8-12, and 55-63 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 February 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 11/8/04 and 11/18/05.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application
- ☐ Other: _____.

DETAILED ACTION***Election/Amendments***

Applicants' elections, with traverse, of Group II (original claims 8-51) and species (A) stochastic computational model and species (E) sensitivity analysis in the response filed 12/6/06 is acknowledged. With regard to the group restriction requirement, the traversal is on the ground(s) that the integrated modeling and simulation of the claims of Groups I and II are capable of being used together and have the same mode of operation, function and effect, e.g., modeling components. Applicant states that the starting points of each group are the same, e.g., constructing a model and, in further like fashion, generating dynamic behavior of the model, and additionally, as Groups I and II are of the same class and sub- class, and a literature search of the Groups I and II would be nearly, if not completely, co-extensive, there would be no serious search burden to the Office. This is not found persuasive. As set forth in the previous Office action on pages 2-3, the inventions of groups I-II are directed to related methods or systems. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the system of group I is drawn to a system for modeling, simulation and analysis of a biological system including constructing a model of the biological system whereas the invention of group II is drawn to a system or method for modeling, simulation and analysis of a biological process including constructing a model of the biological process. A biological system is usually considered as an organism itself as a whole, such as yeast or *Drosophila* or mouse as a biological system for studying genetics. A biological process, however, is any process occurred in a biological system. A model of a system is thus different from a model of a process. Therefore, the two inventions are mutually exclusive, not obvious variants and have different components and certainly

different mode of actions, function and effect. Because these inventions are distinct for the reasons given above, searching of each group requires a distinct strategy, and the searches are thus not coextensive. Thus, whereas the inventions belong to the same classification, they require different search fields, and would impose a serious search burden to the Office if they were examined together.

With regard to the first species election, applicant's traversal is on the ground that the various species mechanisms by which a result of the dynamic behavior of the constructed model is generated are capable of use together and a literature search of all species would be nearly, if not completely co-extensive. This is not found persuasive because each of the species, i.e. each of the different models including stochastic computational model, discrete time-based computational model, and continuous time-based computational model, requires distinct mathematical means, calculations and manipulations. Searching each species thus requires a different search field and are therefore not co-extensive. With regard to the second species election, the traversal is also on the ground that the species are capable of use together and a literature search of all species would be nearly, if not completely co-extensive. This is also unpersuasive. As set forth in the previous Office action, the species, i.e. bifurcation analysis, sensitivity analysis, parameter estimation, non-linear solver, and flux-balance analysis, involve distinct elements and computational steps. It requires distinct mathematical means for each of the analyses. Searching each species thus requires a distinct strategy and field and the searches for the species are thus not co-extensive.

The requirement is still deemed proper and is therefore made FINAL.

The amendment filed 12/6/06 is also acknowledged and entered.

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Claims 1-87 including original claims 1-51 and newly added claims 52-87 are currently pending, but only claims 8-12, 15-18, 20, 22, 26-30, 33-37, 40-43, 45, 47, 52-67 and 77-87 are under examination. Claims 1-7, 13-14, 19, 21, 23-25, 31-32, 38-39, 44, 46, 48-51, and 68-76 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 12/6/06.

Information Disclosure Statement

The Information Disclosure Statements filed 11/8/04 and 11/18/05 have been entered and documents therein have been considered. Initialed copies of the form PTO-1449 are hereby enclosed.

Drawings

The drawings filed 2/20/04 are objected to because of the following informalities:

On the left side of Fig. 8A and 8B is a line of text including "a symbol x 0." The symbol is not legible and it is not clear what it is.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the

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drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The specification is objected to because of the following including informalities:

Applicant is reminded of the proper language and format for an abstract of the disclosure. The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details. In the instant case, legal phraseology "said" is used at least in line 8 of the Abstract on page 51 of the disclosure filed 2/20/04.

Trademarks are used in this application, such as "JBED" on page 9. Trademarks should be capitalized wherever they appear and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks. Applicant is requested to review the entire specification to capitalize all trademarks as appropriate.

The disclosure is objected to also because it contains an embedded hyperlink and/or other form or browser-executable code. Such code is present in the specification at page 20 and elsewhere. Applicants are required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP ' 608.01.

It appears that a comma “,” is missing on page 1, line 31, between the words “processes” and “faces.”

Appropriate correction is required.

Claim Rejections-35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 20-22, 26-30, 45, 47, and 64-67 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The claims are drawn to a process of integrated modeling and simulation of a biological process comprising constructing a model of the biological process in a modeling component, analyzing the constructed model to generate a result and transmitting the result to the modeling component.

The following analysis of facts of this particular patent application follows the rationale suggested in the "Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility" (OG Notices: 22 November 2005, available from the US PTO website at <http://www.uspto.gov/web/offices/com/sol/og/2005/week47/og200547.htm>).

The Guidelines states:

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To satisfy section 101 requirements, the claim must be for a practical application of the § 101 judicial exception, which can be identified in various ways (Guidelines, p. 19):

- The claimed invention "transforms" an article or physical object to a different state or thing.*
- The claimed invention otherwise produces a useful, concrete and tangible result, based on the factors discussed below.*

In the instant case, at least one embodiment of the claimed invention merely manipulates data and performs a series of calculations by mathematical functions for constructing a model and analyzing the model. Thus, the process does not appear to transform an article or physical object to a different state or thing outside a computation device.

Furthermore, the invention does not produce a useful, concrete and tangible result. Specifically it does not produce a tangible result. Since the process merely manipulates data and performs a series of calculations entirely within the confine of a computing device without using or making available for use the results of the manipulation to enable its functionality and usefulness to be realized.

Claim Rejections-35 USC § 112

The following is a quotation of the **first** paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 15-18, 40-43, 52-67 and 77-87 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The amendment filed 12/6/06 added, *inter alia*, claims 52-67 and 77-87 with various new limitations, e.g. annotating the constructed model to add user-provided annotations in claim 52, automatically connecting elements of the model using an auto-connection tool in claim 53, etc. Applicant does not specifically point out, and the Office has not found, sufficient support in the specification for the new claims and the new limitations. They are thus new deemed new matter.

Claims 15-18, 40-43 and 77-78 recite various means-plus-function limitations including “means for constructing a model of a biological process,” “means for generating ... an expected output of the modeled biological process,” and “means for displaying the dynamic behavior,” as recited in claim 15, etc. These “means-plus-function” recitations invoke 35 USC 112, sixth paragraph, which states that a claim limitation expressed in means-plus-function language “shall be construed to cover the corresponding structure...described in the specification and equivalents thereof.” “If one employs means plus function language in a claim, one must set forth in the specification an adequate disclosure showing what is meant by that language.” In the instant case, the specification fails to set forth an adequate disclosure showing what is meant by “means for constructing a model of a biological process,” “means for generating ... an expected output of the modeled biological process,” and “means for displaying the dynamic behavior.” Thus, one skilled in the art would reasonably doubt that the inventor, at the time the application was filed, had possession of the claimed invention.

The following is a quotation of the **second** paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 8-12, 15-18, 20, 22, 26-30, 33-37, 40-43, 45, 47, 52-67, and 77-87 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Independent claims 8, 15, 20, 26, 33, 40 and 45, as well as their dependent claims, recite the limitation that a model "is manipulable by programming language instructions." The metes and bounds of the claimed invention are not clear because the term "manipulable" is a relative term, which renders the claims indefinite. The term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The term "manipulable" is defined in dictionary as "capable of being manipulated" in the Webster-Online Dictionary (retrieved and printed from the internet at <http://www.m-w.com/cgi-bin/dictionary?book=Dictionary&va=manipulable> on 3/1/07). Without a standard and/or criteria in the specification for a model that is capable of being manipulated, it would not be clear to one skilled in the art whether or not a particular model is manipulable by programming language instructions.

As set forth above, claims 15-18, 40-43 and 77-78 recite "means-plus-function" limitations, thus invoking 35 USC 112, sixth paragraph.

The MPEP 2181(II) states:

If an applicant fails to set forth an adequate disclosure, the applicant has in effect failed to particularly point out and distinctly claim the invention as required by the second paragraph of section 112." In re Donaldson Co., 16 F.3d 1189, 1195, 29 USPQ2d 1845, 1850 (Fed. Cir. 1994) (in banc).

In the instant case, the specification does not provide an adequate disclosure showing the structure, material or acts for these "means-plus-function" limitations, for reasons as set forth above. Thus, one skilled in the art would not know what are meant by these "means-plus-function" limitations, and the metes and bounds of the claimed invention are thus unclear.

Clarification of the metes and bounds of the claims is requested.

Claim Rejections-35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 8-12, 15-18, 20, 22, 26-30, 33-37, 40-43, 45, 47, 52-67 and 77-87 are rejected under 35 U.S.C. § 102(b) as being anticipated by Kelly et al. (IDS document: WO 03/001891, 09 January 2003).

The claims are drawn to a method and system for modeling and simulation of a biological process comprising constructing a model of a biological process, generating using the model dynamic behavior of the modeled biological process, and displaying the dynamic behavior on a display device.

Kelly et al. disclose a method and system for modeling and simulation of immune system including various biological processes. The method comprises providing data using graphical user interface and constructing a model of the immune system comprising components of immune responses using various mathematical equations including stochastic differential equations and Effect Diagram (see at least pages 9, 15), validating the model and using the model to produce simulated biological attributes associated with the biological state of the immune responses and compare simulated biological attributes with a corresponding biological attribute of a reference pattern of the immune response, which simulated biological attributes are interpreted as being dynamic behavior of the modeled process. See at least Fig. 3 and pages 43-

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44. These are displayed in the various drawings disclosed by Kelly et al. Furthermore, as the modeling, simulation and validation are also performed in computer systems with monitors and other display devices, all the results would be inherently displayed in the display devices involved. The Effect Diagram used in the modeling is considered a block diagram. Kelly et al. also disclosed the computer system and computer programs including codes for executing the method of modeling and simulations. See at least pages 41-42.

Provisional Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 8-12, 15-18, 20, 22, 26-30, 33-37, 40-43, 45, 47, 52-67 and 77-87 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 8-36 of US copending Application No. 10/783,552 (now publication US20050187746).

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claims because the examined claim is either anticipated by, or would have been obvious over, the reference claims. See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The claims are drawn to a method and system for modeling and simulation of a biological process comprising constructing a model of a biological process, generating using the model dynamic behavior of the modeled biological process, and displaying the dynamic behavior on a display device.

While there are apparent differences in wording and minor limitations due to the amendment to the instant claims filed 12/6/06, the claims of the instant application under consideration are anticipated by claims 8-36 of US copending Application No. 10/783,552. The independent claim 8 of copending Application No. 10/783,552 claims a method for modeling and simulation for a biological process comprising (a) providing a graphical user interface for

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accepting user commands, (b) receiving, via the provided user interface, user commands and data; (c) constructing, using the received user commands and data, a model of the biological process; (d) generating, using the constructed model of the biological process, dynamic behavior of the modeled biological process; and (e) displaying the dynamic behavior of the biological process on a display device. This method with specific steps anticipates the method of the instant claims.

Claim Objections

Claims 8-12, and 55-63 are objected to because of the following reasons including informalities:

Independent claim 8 recites “constructing a model of a the biological process... (emphasis added by the examiner).” It appears the article “a” should be deleted. Claims 9-12 and 55-63 are objected to as being dependent from claim 8 and thus comprising the limitation.

Appropriate correction is required.

Conclusion

No claim is allowed.

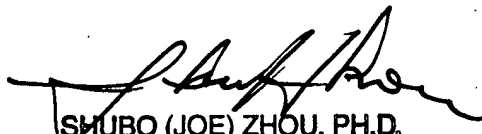
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shubo (Joe) Zhou, whose telephone number is 571-272-0724. The examiner can normally be reached Monday-Friday from 8 A.M. to 4 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem (Remy)

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Yucel, Ph.D., can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

sz/SZ



SHUBO (JOE) ZHOU, PH.D.
PATENT EXAMINER